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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/748,706	12/22/2000	Mark S. Chee	A-66828-5/DJB/RMS/DCF	4006

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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 02/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/748,706

Applicant(s)

CHEE ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-49 is/are pending in the application.
- 4a) Of the above claim(s) 27-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/03</u> . | 6) <input type="checkbox"/> Other: _____ |

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 26 November 2003 in which new claims 35-44 were added. New Claims 35-44 have been renumbered Claims 40-49 according to 37 C.F.R. 1.126.

The previous objections rejections in the Office Action dated 25 September 2002 are withdrawn in view of the amendments filed 25 February 2003 which canceled the rejected claims and amended the specification. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the canceled claims and new grounds for rejection. New grounds for rejection necessitated by the addition of new claims are discussed.

Claims 1-26 are canceled.

Claims 27-39 are withdrawn.

Claims 40-49 are under prosecution.

Specification

2. Applicant's amendment to the specification filed 25 February 2003 is acknowledged. The amendments have been entered. The previous objection is withdrawn.

Priority

3. Applicant's comments regarding the provisional application 60/060,473 and parent application 09/189,543 are acknowledged. As Applicant notes, the provisional and parent

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applications teach a FACS decoding system. However, it is maintained that the teaching of a FACS decoding system does not support the instantly claimed "liquid array".

Applicant has provided Appendix A-D to illustrate that liquid array were known in the art and that FACS is a liquid array. Applicant's comments have been considered but the evidence provided is not sufficient to illustrate that a teaching of FACS support the instantly claimed liquid array for the following reasons. Applicant states (page 6, lines 7-10 of the response) that one of skill would have "understood that FACS is a liquid array". While it may be true that FACS is a liquid array, the provisional and parent applications do not teach that FACS is a liquid array. Furthermore, the teaching of a single species of a liquid array i.e. FACS does not teach the genus of liquid arrays. Instant Claim 47 is drawn to a liquid array. The provisional and parent applications do not teach or describe the meets and bounds encompassed by the instantly claimed "liquid array". As such, the provisional and parent applications do not provide adequate support under 35 U.S.C. 112 for the instantly claimed liquid array.

It is further noted that if Applicant equates FACS and "liquid array", then it would appear that Claims 42 and 43 are duplicate claims.

The effective filing date for instant Claim 47 is the filing date of parent application 09/344,526 i.e. 24 June 1999.

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Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 40-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Kamb et al U.S. Patent No. 6,060,240, filed 13 December 1996).

Regarding Claim 40, Kamb et al disclose a method comprising: providing an array composition comprising a population of microspheres comprising at least a first and second subpopulation each comprising a bioactive agent (i.e. capture probes complementary to the identifier tags on the tagged cDNA, Column 23, lines 30-33) and a first and second decoding attribute (i.e. labeled cDNAs and labeled free identifier tag sequences, Column 23, lines 30-45) and detecting each of said decoding attributes to identify each of said bioactive agents (Column 22, line 58-Column 23, line 64 and Fig. 15 B).

Regarding Claim 41, Kamb et al disclose the method wherein the first decoding attribute comprises detecting binding of an identifier binding ligand (i.e. labeled cellular cDNA, Column 23, lines 27-33).

Regarding Claim 42, Kamb et al disclose a method comprising: providing an array composition comprising a population of microspheres comprising at least a first and second subpopulation each comprising a bioactive agent (i.e. capture probes complementary to the identifier tags on the tagged cDNA, Column 23, lines 30-33) and a first and second decoding attribute (i.e. labeled cDNAs and labeled free identifier tag sequences, Column 23, lines 30-45)

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and detecting each of said decoding attributes to identify each of said bioactive agents (Column 22, line 58-Column 23, line 64 and Fig. 14) wherein the first decoding attribute comprises detecting binding of an identifier binding ligand (i.e. labeled cellular cDNA, Column 23, lines 27-33) and detecting binding of a first target analyte to the bioactive agent on the microsphere (i.e. tagged cDNA binding to the capture probe (Column 23, lines 20-35).

Regarding Claim 43, Kamb et al disclose the method wherein the IBL comprises a nucleic acid i.e. tagged cDNA (Column 23, lines 21-64).

Regarding Claim 44, Kamb et al disclose the method wherein the second decoding attribute is a second IBL (i.e. labeled free identifier tag sequences, Column 23, lines 30-45).

Regarding Claim 45, Kamb et al disclose the method wherein the first and second attributes are IBLs and are attached to the first and second subpopulations of microspheres at first and second ratios (Column 23, lines 45-64).

Regarding Claim 46, Kamb et al disclose the method wherein the microspheres are distributed on a substrate e.g. 96 well plate following FACS sorting (Fig. 14).

Regarding Claim 47, Kamb et al disclose the method wherein the array is a liquid array i.e. assays are carried out in solution (Column 23, lines 20-64 and Fig. 14).

Regarding Claim 48, Kamb et al disclose the method wherein said detecting is by FACS (Example 14, Column 37, lines 30-51 and Fig. 14).

Regarding Claim 49, Kamb et al disclose the method wherein the bioactive agent and IBL are different molecule i.e. the bioactive agent is the capture probe and the IBL are tagged cDNAs and labeled free tags (Column 23, lines 20-64 and Fig. 14).

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6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

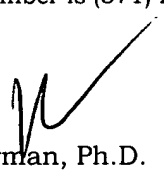
7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741 until 13 January 2004. The examiner can normally be reached on 6:00 TO 3:30 Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-8724 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-0507.



BJ Forman, Ph.D.
Primary Examiner
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February 3, 2004